

Health Information Technology Policy Committee Summary of the May 19, 2010, Meeting

KEY TOPICS

1. Call to Order

Judy Sparrow, Office of the National Coordinator (ONC) welcomed participants to the 12th meeting of the Health Information Technology Policy Committee (HITPC). She reminded the group that this was a Federal Advisory Committee meeting and was being conducted in public.

2. Opening Remarks

National Coordinator for Health Information Technology David Blumenthal reported that 15 awards have been announced for the Beacon Award grant initiative, for which the ONC received 130 applications. Soon there will be another, smaller round of grants announced, totaling approximately \$30 million. This second round was initiated in response to the enthusiasm of the community for these grants and the number of qualified but unfunded applications submitted in round one.

3. Review of the Agenda

HITPC Co-Chair Paul Tang reviewed the day's agenda, which featured a series of workgroup updates. He then asked for and received approval of the minutes from the last meeting (held on April 21, 2010).

Action Item #1: The Committee approved the minutes from April 21, 2010, HITPC meeting by consensus.

4. Strategic Plan Workgroup: Health IT Strategic Framework

Paul Tang reminded the group that the ONC was required to update its strategic plan. The Strategic Plan Workgroup was asked to generate and propose a set of recommendations in this regard. The Workgroup held nine meetings as well as public listening sessions that generated numerous comments. This input was incorporated into the Workgroup's document.

One of ONC's roles is in producing the infrastructure for health care, although it does not provide any health care directly. Policy and technical infrastructure serve as the base components in a strategy that is aimed at creating a learning health system. Additional components include privacy and security and the meaningful use of HIT. For each of these components, a series of objectives and strategies were presented.

An extensive discussion followed, including these highlights:

- Judy Faulkner suggested that Strategy 1.1.1 should focus solely on creating a policy framework, rather than coupling policy with standards and services under Strategy 1.1.3. She commented that it is easier to focus on technology and standards than it is to address policy-related issues; therefore the policy work may tend to be less emphasized.
- Gayle Harrell noted that Strategy 1.1.2 proposes an incremental approach, which is appropriate for many areas but not for privacy and security. Privacy and security should be identified separately as being foundational, and not incremental.
- Neil Calman noted that the strategic framework does not appear to be as accessible compared with other HITPC efforts. He suggested tying the objectives and strategies into the language being used to describe the meaningful use goals. He also suggested that the overarching goals could be more clearly presented as supporting the intended outcome the HITPC and ONC are working towards. In addition, a “translated” version of this framework for public consumption would make it easier for those not involved in the Workgroup’s deliberations to more fully understand the objectives and strategies.
- Paul Tang explained that the intended audience for this document is the ONC. Efforts were made to address public accessibility in the preamble. He pointed out that in Strategy 3.3.1, the Workgroup discusses a comprehensive communication strategy. The ONC is aware that open communication with the public is necessary.
- It was suggested that Strategy 3.4.1, addressing the efficiency of the health care system, should also include the harmonization of all data reporting. Many of the meaningful use criteria point in this direction, but there are existing reporting requirements in place that do not assume the existence of electronic health records (EHRs).
- David Lansky was asked about accountability of the various key entities, including ONC, the Department of Health and Human Services, and the Centers for Medicare and Medicaid Services (CMS) in accomplishing the goals. The goals are very ambitious, and are not necessarily measurable or “trackable.” It would be helpful to indicate what will be accomplished by a given date. He also noted that additional information on funding is required. The issues of payment reform within HIT space, the dynamics of the marketplace, and the role of federal and state agencies all need to be considered and leveraged.
- Paul Eggerman suggested that Objective 1.1 does not address incrementally improving privacy and security; rather, it focuses on incrementally improving security. This distinction is important, because as functionality incrementally changes over time, security will be incrementally enhanced. He commented that he feels the language in this Objective is acceptable as written.
- Paul Eggerman also noted that Strategy 1.3.3 focuses on monitoring patient safety concerns related to HIT. He suggested that the language could be reworded to indicate the intent to both monitor and address patient safety concerns related to HIT.

- Judy Faulkner explained that this plan could be seen as morphing into potential government control in the development of EHRs. For example, Objective 1.1 refers to enhancing EHR functionality and utility. This process will define the direction of EHR functionality. She expressed concern that leaving it to the open market to define functionality may be a better approach.
- Christine Bechtel suggested replacing every reference to “behavioral change” with “cultural change” throughout the document. “Behavioral change” can be interpreted negatively by consumer communities. The Workgroup can communicate the same message by broadening the notion to improving health, rather than just “changing behavior.” Also, under the shared decision making strategy (Objective 3.3), she suggested adding “and appropriate linkages to educational resources” to the end of the objective’s text.
- David Blumenthal commented that some HITPC members’ input was leaning towards implementation guidance. This is valuable input, but it is not within the scope of this strategic plan.
- It was suggested that the strategic plan include a reminder that HIT will improve the cost profile of health care. There should be some reference to the value of this public investment, and that it justifies Congress’ commitment in this area.
- In response to a question by LaTanya Sweeney, David Blumenthal explained that the plan provides a set of goals against which ONC and HITPC can strategize and form tactics. This activity involves policymaking at every level, and informs budget development on an annual basis. The ONC will be asked to justify how its budget furthers this plan.
- Gayle Harrell commented that the ONC and HITPC must take care to prevent the plan from becoming a mechanism for rationing health care or limiting appropriate care. The plan discusses HIT offering tools to collect and manage data to facilitate getting the “right” care. This could be interpreted differently depending on who is reading it (e.g., the payer, the patient). Improving quality of care needs to be at the center of this.

Action Item #2: ONC staff and Strategic Plan Workgroup members will develop another draft based on this input. The new version will either come back before the Committee, or there will be a teleconference before it is approved for transmittal to the ONC.

5. Information Exchange Workgroup Update

Micky Tripathi reported that the Information Exchange Workgroup hopes to finalize its agenda for the rest of the year and align with the other interoperability groups as well as with the HIT Standards Committee (HITSC) agenda as related to interoperability issues. It would be beneficial to adjust the Workgroup membership to establish some type of communication channel for state-level HIT decision makers.

With respect to the Workgroup's scope and approach, they can be most helpful in the areas of labs, e-prescribing, public health, administrative transactions, summary exchange transactions, reporting, and patient-facing applications. For each of these, Workgroup members will examine a series of questions to create an evaluative framework. The policy levers that can be used are services, standards, policies, and trust fabric.

Micky Tripathi presented a slide with some raw feedback from various state-level HIT coordinators, with suggestions on what they feel the Workgroup should address. Some of these issues should not necessarily reside within this Workgroup, but they are still useful to note.

The next steps recommended for the Information Exchange Workgroup include:

- Adjust the plan moving forward according to suggestions made at this meeting.
- Adjust the Workgroup structure and composition to better fit its future agenda (e.g., membership changes, HIT Coordinators Advisory Panel).
- Work with the Nationwide Health Information Network and Privacy and Security Policy Workgroups on a coordinated interoperability agenda for the next 3-6 months. Proposed priority areas include public health, labs, Medicaid coordination, and summary exchange transactions.
- Present a new work plan and Information Exchange Workgroup structure/membership changes at the June 25, 2010, HITPC meeting.

The discussion that followed included these highlights:

- Judy Faulkner expressed concern with state-by-state variation (e.g., one state may adopt a rule, another state may not). She also pointed out that many organizations serve people in multiple states. She asked whether thought had been given to creating a small number of regions throughout the United States to limit the amount of confusion/variance. David Blumenthal noted that Congress requires that a minimum amount of money be spent on state-based or state-designated entities to work on health information exchange (HIE). Ideally, a policy addressing cross-state information exchange will be developed in the near future.
- Deven McGraw cautioned that this group not become the equivalent of a "State HIE Workgroup." There are additional targeted issues that need to be addressed and are not necessarily exclusive to the states.

Action item #3: The Committee accepted the Information Exchange Workgroup's recommended next steps.

6. Meaningful Use Workgroup Update

Paul Tang reminded HITPC members that there are three stages of meaningful use. On April 20, the Meaningful Use Workgroup held a hearing on patient and family engagement. Following this hearing, the group received additional input on its Federal Advisory Committee blog (input can still be submitted). The primary messages conveyed in this input includes: (1) the time for incremental movement is over, (2) people want more access and more engagement now, (3) engage with the public about meaningful use, (4) encourage innovation, (5) create a sense of community among patients and the health team, and (5) focus more on patient outcome measures

Paul Tang then shared the Workgroup's tentative 2010 timeline, which includes a discussion of preliminary Stage 2 and 3 meaningful use criteria in September, presenting proposed Stage 2 and 3 criteria to the HITPC in October, and the HITPC issuing a Request for Information on preliminary Stage 2 and 3 criteria in November. By the second quarter of 2011, it is hoped that the HITPC will finalize Stage 2 and 3 recommendations to the ONC.

In discussion, the following points were made:

- Paul Egberman noted that at its last meeting, the HITPC approved an Adoption Certification Workgroup recommendation that Stage 2 recommendations would be available in April of 2011.
- It was suggested that the Workgroup could insert a step in September that would create a Wiki or similar mechanism that could be used to organize the information from a variety of organizations that are drafting documents suggesting what should be done for Stages 2 and 3. This Wiki would allow the Workgroup to bring that information into its process.
- It also was suggested that the Workgroup could now start developing the key set of questions that will need to be answered in terms of information needed. What are people saying externally? What is being said in the panels? What will the mapping process be once the final rule is published?
- Gayle Harrell noted that the Workgroup will have to examine individual states' rights unless there is a federal pre-emption of those laws. Privacy and security is a key element with respect to patient access to information. Efforts must be made to ensure that those privacy and security requirements are built in.
- Lessons could be learned from early adopters. It was suggested that recent recipients of Beacon Community and Sharp grants could be looked to for guidance in this area.

7. Privacy and Security Policy Workgroup Update

Deven McGraw emphasized that privacy and security are foundational. A comprehensive set of privacy and security protections that build on current law is critical to building a foundation of trust that will support meaningful use. In addition, consent is just one piece of a larger puzzle. If

consent is taken to be the most important protection, individuals might end up bearing the burden of protecting their own privacy, which could be very complicated.

Deven McGraw explained that there are different types of exchange, and that in a one-to-one exchange, one provider sends information to another to facilitate treatment. There is no intermediary. This scenario comes closest to the present circumstances. There is an exchange type involving an entity that facilitates these exchanges. It is not clear that current law adequately addresses the activities of such facilitators.

The Workgroup presented the following recommendations:

- We need specific policies, as well as technology requirements, to govern all forms of electronic HIE.
 - Implement the Nationwide Privacy and Security Framework principles.
 - Work should take place ideally before, or at least in conjunction with, technology standards work. Technology should implement policy and not make it
 - Fill gaps in current law.
 - Address “facilitator” access to identifiable information—constraints on collection, access, and use of identifiable data; constraints on data retention and re-use; and security requirements.
- One-to-one exchange from one provider to another for treatment purposes—even with no “facilitator”—must be governed by policies that at least include:
 - Encryption (no ability for facilitator to access content). Encryption ideally should be required when there is the potential for transmitted data to be exposed (mandate through meaningful use/certification criteria or Health Insurance Portability and Accountability Act [HIPAA] security rule modification).
 - Limits on identifiable (or potentially identifiable) information in the message.
 - Identification and authentication.
- If strong policies such as the above are in place and enforced, we do not think the above scenario needs any additional individual consent beyond what is already required by current law.

The group has identified more questions that need to be resolved, with respect to enforcing requirements on “facilitators.” Many of these will be business associates, but there could be limits to the reach of business associate provisions. For example, they do not cover subcontractors of business associates; the balance of power in determining the terms of agreement may be with the business associates; and current business associate rules do not dictate specific terms regarding the access, use and disclosure of personal health information. Additional issues and questions facing the Workgroup include the fact that meaningful use/certification criteria do not reach entities that are not participating in the incentive program, the role states can and should play, NHIN governance, and the role of the data use and reciprocal support agreement.

Additional Workgroup efforts are needed to drilling down on specific policies and technology requirements for all models of exchange—this activity will be carried out in conjunction with HITPC’s Information Exchange and NHIN Workgroups. Future efforts will also focus on the role that consent plays in non-direct models such as central database and query/response, an examination of consent at a more granular level (such as by data type), transparency for patients, and “de-identified” data issues.

The following points were made in discussion:

- Rachel Block noted that attention must be paid to the administrative and workflow requirements associated with these decisions so that the Workgroup does not recommend actions from a policy perspective that could not be implemented from a technical standpoint.
- In response to a question from David Blumenthal, Rachel Block commented that states’ needs are consistent with what has been outlined in this presentation. Decisions will need to be made with regard to what kinds of policies should apply under different HIE scenarios. Creating a mechanism to help states determine what sorts of policies at a minimum may be appropriate is also needed. There will be a rolling set of requirements at the same time that the policy framework itself will be evolving—this will cause confusion for states, stakeholders, and consumers.
- David Lansky commented that California needs to have many of these questions answered by October, and will have to provide its own answers if there is no guidance from the federal government soon.
- It was suggested that the Workgroup needs a staff resource for the aggressive policy development tasks to help bring state-of-the-art information to the Workgroup for deliberation. Also needed is a feedback loop to practitioners who are facing these issues operationally. There could be an aggressive drafting process with consultants or others, to be directed by the Workgroup and then sent out for consideration.
- Adam Clark pointed out that the expectations of a “reasonable” patient are hard to define, given that someone who has just been told they have cancer will have a very different level of “reason” than a patient with a much less serious diagnosis.
- Paul Eggerman asked about the second recommendation and whether the Workgroup is recommending that ONC alter the HIPAA Privacy Rule. Deven McGraw indicated that one way to implement it would be to push for a modification to the security rule in HIPAA. At a minimum, the transmission pipeline should be encrypted. The most effective way to have this enforced is a governance matter.
- Tony Trenkle commented that one issue related to encryption is sending time-critical information that the receiving party may not be able to de-encrypt.
- In response to a question, Deven McGraw confirmed that focusing the Workgroup’s attention first on intermediaries might be a good idea.

- David Blumenthal acknowledged the Workgroup's heavy load and its time crunch. He suggested that some guidance in the areas of consent and common models of exchange—specifically NHIN Direct and NHIN Exchange—would be a good start. There is the question of how states can move data back and forth from one state to another, and the question of what needs to happen in order to create the trust environment necessary for the first stage of meaningful use. What is the threshold that needs to be reached for 2013, when this set of responsibilities is revisited?

8. NHIN Workgroup Update

David Lansky explained that the NHIN Workgroup is currently preparing a draft letter to the HITPC for referral to the National Coordinator. This will be discussed further at the next Committee meeting.

The Workgroup has been considering how to most effectively apply NHIN Direct to the real world. This application collides with a series of privacy and security issues, many of which have been discussed during this meeting. The Workgroup's framework raises questions centered on technical requirements, oversight to support policy goals, and governance. The Workgroup has started to examine NHIN Direct as a first test case for its framework, which has triggered some unexpected questions. In the next few weeks, the NHIN Workgroup will begin to address these questions, and possibly re-craft its workload to provide some help or answers for the other HITPC workgroups.

9. ONC Update

Jodi Daniel discussed the new Enrollment Workgroup. ONC was specifically asked by Congress to set up a list of standards for getting people enrolled in federal and state insurance programs. Enrollment Workgroup members will be pulled from both the HITPC HIT Standards Committee (HITSC), with additional outside experts. The Workgroup will meet biweekly, beginning in June, to look at what is needed to scope policy decisions and to identify the kinds of information for which standards should be developed. The Workgroup will make recommendations to this the HITPC first, then to the HITSC, in order to be ready by September (which is the Workgroup's 180-day deadline). Aneesh Chopra and Sam Carp will serve as Enrollment Workgroup Co-Chairs.

David Blumenthal asked HITPC members to think about people who do not have insurance but who would want to get insured. Where do they have government contact now? In places like the Women, Infants, and Children Program; Head Start; schools; motor vehicle departments; and the range of social service organizations. Ideally, these individuals would be channeled towards the health care program for which they are eligible. The Enrollment Workgroup will consider how to make this process as easy as possible.

LaTanya Sweeney noted that the outcome of this work can have a significant impact on authentication and identification. It could drastically change design issues, and underscores the need to integrate privacy and the NHIN.

10. Public Comment Session

Chantel Worzala of the American Hospital Association commented on the strategic plan document, and the Meaningful Use Workgroup. With regard to the strategic plan, she emphasized the coordination component, noting that there are many parts of the government that affect and control enforcement of the activities the HITPC is considering. She emphasized the need to clearly delineate which group is responsible for which activity within the plan. In terms of meaningful use, she suggested conducting an assessment of market readiness for those areas in which HITPC is looking to increase requirements. She urged Committee members to consider readiness across the whole spectrum, not just high-end academic research institutions, and expressed hope that market assessment will be included as this initiative progresses. Chantel Worzala also encouraged the Meaningful Use Workgroup to consider all of its recommendations in the context of the recently passed health reform bill.

Fassel Karashim, an independent health care consultant, asked for more clarity regarding the differences in roles between state HIT and the meaningful use regulations with regard to business associates.

SUMMARY OF ACTION ITEMS:

Action Item #1: The Committee approved the minutes from April 21, 2010, HITPC meeting by consensus.

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